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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/998,966

Applicant(s)

SHIMKETS ET AL.

Examiner

Olga N. Chernyshev

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☒ Claim(s) 14 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11/16/02 01 10/31/01
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1646

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 7 is acknowledged.

Claims 16 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 7.

Claims 1-15 are under examination in the instant office action.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration, see the citizenship and address corrections of inventor Ferenc Boldog. See 37 CFR 1.52(c).

Specification

3. Applicant is advised that the substitute specification provided in Paper No. 4, filed on July 03, 2002, has not been entered because it lacks pages 12-21. Applicant is required to provide a complete substitute specification in response to this office action.
4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see page 5, line 18. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Art Unit: 1646

5. The use of the trademarks on page 71, lines 2-3 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Objections

6. Claims 14 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to other claims in the alternative only. See MPEP § 608.01(n). Claim 15 depends from claim 14. Accordingly, claims 14-15 are not been further treated on the merits.

Claims 1-13 are under examination in the instant office action.

7. Claims 3, 4, 7, 8 and 9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 3, 4, 7, 8 and 9 are directed to a compliment of the nucleic acid of claim 1 and, therefore, claims 3, 4, 7, 8 and 9 can be infringed by a nucleic acid, which does not infringe claim 1. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant should note the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything, which would not also infringe the basic claim. In the

Art Unit: 1646

instant case, the complement nucleic acid claims could be infringed without infringing the claim from which it depends, i.e. the sense nucleic acids claim. Therefore, they are improperly dependent and should be rewritten in independent form.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 7 and 8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 7 is directed to an oligonucleotide sequence. Applicant is advised that “a sequence” is a property of the material substance and not a substance itself, therefore, it is not a “composition of matter”.

In case an oligonucleotide is claimed, then the claims fail to include any limitations which would distinguish the claimed proteins, peptides and compositions from those which occur in nature. In the absence of the hand of man, naturally occurring nucleic acid molecules and proteins are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Additionally, mere purity of a naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui, 156 USPQ 426 (1966). However, when purity results in a new utility, patentability is considered. Merck Co. v. Chase Chemical Co., 273 F. Supp. 68 (1967). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment of the claims to recite a purity limitation, if supported by the

Art Unit: 1646

specification, is suggested to obviate this rejection. Applicant should point to the basis in the specification for any amendment to the claim.

9. Claims 1-13 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

It is clear from the instant application that the polypeptide described therein is what is termed an "orphan protein" in the art. The DNA of the instant application has been isolated because of its similarity to a known DNA. There is little doubt that, after complete characterization, this DNA and encoded protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process

Art Unit: 1646

is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to an isolated nucleic acids encoding protein of as yet undetermined function or biological significance. It is clear from the instant application that the SEC1 protein (clone ID NO. FGF10AC004449) of SEQ ID NO: 2, encoded by a nucleic acid of SEQ ID NO: 1, is one of the SECX proteins of the invention. SEC1 polypeptide is 170 amino acids long and shares 54% identity to the Human Fibroblast Growth Factor 10 precursor, also known as Keratinocyte growth Factor 2 (page 9, lines 23-26 of the instant specification). It is also stated that SEC1 of the instant invention also "has high similarity to several segments from a human metalloprotease thrombospondin 1" (page 10, lines 22-23). Thus, based on the structural similarities to different known proteins with well-established function, it has been suggested that the NHP of the instant invention would also possess similar biological activity, namely the activity of a fibroblast growth factor (FGF) or a human metalloprotease METH1.

The assertion that the disclosed SEC1 has biological activities similar to known human growth factors or metalloproteases is not substantial in the absence of supporting evidence, because the relevant literature reports numerous examples of polypeptide families wherein individual members have distinct, and even opposite, biological activities. For example, Tischer et al. (U.S. Patent 5,194,596) establishes that VEGF (a member of the PDGF, or platelet-derived growth factor, family) is mitogenic for vascular endothelial cells but not for vascular smooth muscle cells, which is opposite to the mitogenic activity of naturally occurring PDGF which is mitogenic for vascular smooth muscle cells but not for vascular endothelial cells (column 2, line

Art Unit: 1646

46 to column 3, line 2). The differences between PDGF and VEGF are also seen *in vivo*, wherein endothelial-pericyte associations in the eye are disrupted by intraocular administration of PDGF but accelerated by intraocular administration of VEGF (Benjamin et al., 1998, Development 125:1591-1598; see Abstract and pp. 1594-1596). Similarly, PTH and PTHrP are two structurally closely related proteins, which can have opposite effects on bone resorption (Pilbeam et al., 1993, Bone 14:717-720; see p. 717, second paragraph of Introduction). Finally, Kopchick et al. (U.S. Patent 5,350,836) disclose several antagonists of vertebrate growth hormone that differ from naturally occurring growth hormone by a single amino acid (column 2, lines 37-48).

Generally, the art acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases. For example, Skolnick et al. (2000, Trends in Biotech. 18:34-39) state that knowing the protein structure by itself is insufficient to annotate a number of functional classes, and is also insufficient for annotating the specific details of protein function (see Box 2, p. 36). Similarly, Bork (2000, Genome Research 10:398-400) states that the error rate of functional annotations in the sequence database is considerable, making it even more difficult to infer correct function from a structural comparison of a new sequence with a sequence database (see especially p. 399). Such concerns are also echoed by Doerks et al. (1998, Trends in Genetics 14:248-250) who state that (1) functional information is only partially annotated in the database, ignoring multi functionality, resulting in underpredictions of functionality of a new protein and (2) overpredictions of functionality occur because structural similarity often does not necessarily coincide with functional similarity. Thus,

Art Unit: 1646

according to the state of the art, functional characteristics of a protein cannot be unequivocally extrapolated from its structural characteristics.

The instant specification fails to describe the biological role of the polypeptide SEC1 encoded by the claimed nucleic acids. Therefore, the assertion that "SEC1 nucleic acids and polypeptides may be useful in treating of cancer and other disorders related to angiogenesis including abnormal wound healing, inflammation, rheumatoid arthritis, psoriasis, endometrial bleeding disorders, diabetic retinopathy, some forms of macular degeneration, haemangiomas, and arterial-venous malfunctions" (page 10, lines 25-28 of the instant specification) is found to be unsubstantiated. There is no evidence of record, presented in the instant specification as filed, which associates the instant nucleic acids encoding SEC1 polypeptide or the polypeptide itself with any disease or disorder. The assertion that SEC1 protein could be used in methods of treatment of certain pathological conditions has no basis because the specification fails to teach the specific biological activity of SEC1 protein, and, therefore, use of SEC1 in treatment would not be specific substantial or credible as no diseases have been identified which correlate to the claimed invention. The instant application also fails to demonstrate use of the instant nucleic acids or the encoded protein as a marker for any disease or condition (which would be a real world use). Because the instant specification does not teach a biological activity of the protein, one cannot prevent or treat a condition or disease as implied by the specification.

To employ nucleic acids of the instant invention in any of the disclosed methods, such as predictive medicine or diagnostic assays, as implied by the instant specification, would clearly be using it as the object of further research, which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a

Art Unit: 1646

specific, substantial and credible use for the instant nucleic acids or the encoded protein, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.
11. Claims 1-13 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites a nucleic acid, which 90% identical to a nucleic acid sequence encoding a polypeptide of SEQ ID NO: 2 or a fragment of it. Claims 3, 6 and 12 recite “a mutant or a variant” of the nucleic acid that encodes a polypeptide of SEQ ID NO: 2. Claims 8 and 9 recite “a portion” of polynucleotide of SEQ ID NO: 1. Claims 2, 4, 5, 7, 10-11 and 13 are dependant claims. The instant specification fails to describe the entire genus of nucleic acids, which are encompassed by these claims. In making a determination of whether the application complies

Art Unit: 1646

with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a nucleic acid molecule which encodes a protein which has the amino acid sequence of SEQ ID NO: 2. This nucleic acid molecule has a nucleic acid sequence of SEQ ID NO: 1. The subject matter, which is claimed, is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are nucleic acids having 90% identity to, or mutants, variants or fragments of a nucleic acid encoding a polypeptide of SEQ ID NO: 2, or portions of SEQ ID NO: 1. First, the claims are not limited to a polynucleotide with a specific nucleic acid sequence. The claims only require the polynucleotide to share some degree of structural similarity to the isolated nucleic acid of SEQ ID NO: 1, which encodes a polypeptide of SEQ ID NO: 2. The specification only describes a polynucleotide having the nucleic acid sequence of SEQ ID NO: 1 and fails to teach or describe any other polynucleotide, which lacks the nucleic acid sequence of SEQ ID NO: 1 and is capable to encode a polypeptide with functional activity of a polypeptide of SEQ ID NO: 2. Therefore, there is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the prior art.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was

Art Unit: 1646

filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the polynucleotide of SEQ ID NO: 1. The specification does not provide a complete structure of those nucleic acids having 90% identity to, or mutants, variants or fragments of a nucleic acid encoding a polypeptide of SEQ ID NO: 2, or portions of SEQ ID NO: 1. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus (those nucleic acids having 90% identity to, or mutants, variants or fragments of a nucleic acid encoding a polypeptide of SEQ ID NO: 2, or portions of SEQ ID NO: 1) because the specification teaches only the one embodiment of SEQ ID NO: 1. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 3, 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1646

13. Claims 5 and 6 are indefinite because the metes and bounds of the recitation “an amino acid of SEQ ID NO: 2” cannot be determined.

14. Claim 6 is indefinite and ambiguous for recitation of hybridization “under stringent conditions”. Without providing a precise set of hybridization conditions, in the claim or the specification, the metes and bounds of the claimed isolated nucleic acid molecule cannot be defined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1, 2, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Hopp et al., US Patent 5,011,912, 1991.

Claim 1 (d) is directed to a fragment of the nucleic acid comprising a sequence that is 90% identical to the nucleic acid sequence encoding a polypeptide of SEQ ID NO: 2, such fragment at least 20 nucleotides long. Claim 2 merely limits the nucleic acid of claim 1 to DNA or RNA. Due to the open language of the claim and the fact that 10% of the nucleic acid encoding a polypeptide of SEQ ID NO: 2 represent 67 nucleotides, it is clear that the claimed fragment encompasses any known polynucleotide in general or any known polynucleotide encoding a polypeptide of at least 5 amino acids long, such as the polynucleotide encoding a polypeptide disclosed by Hopp et al. (see column 6, lines 4-5).

Art Unit: 1646

Similarly, claim 8 and 9 comprise a sequence complementary to only a portion of the nucleotide sequence of SEQ ID NO: 1, with no size limitation. Therefore, the claimed subject matter is anticipated by any nucleic acid, such as disclosed by Hopp et al.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

16. Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 01/18228 document published on March 15, 2001. Please note that only the first page of this document is provided to Applicant.

Claims 1-6 are directed to a nucleic acid encoding a polypeptide of SEQ ID NO: 2. WO 01/18228 document discloses an amino acid sequence, which is 100% identical to SEQ ID NO: 2 (see a copy of the printout of the sequence alignment attached to the instant office action). Thus WO 01/18228 anticipates claims 1-6.

With regards to the priority date, Applicant is advised that the instant application can only receive benefit under 35 U.S.C. § 120 from an earlier application which meets the requirements of 35 U.S.C. § 112, first paragraph, with respect to the now claimed invention.

35 U.S.C. § 120 states that:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

Because the instant application does not meet the requirements of 35 U.S.C. § 112, first paragraph for those reasons given above, the priority to the earlier provisional application is

Art Unit: 1646

denied. Therefore, the effective filing date of the instant application is established as the filing date of the instant application, which is 10/31/2001.

Double Patenting

17. Applicant is advised that should claim 7 be found allowable, claim 8 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 8 encompasses an oligonucleotide that is complementary to at least a portion of the nucleotide sequence of SEQ ID NO: 1. Applicant is advised that "a portion" encompasses a fragment as small as one nucleotide. Therefore, any oligonucleotide of claim 8 would have at least one nucleotide that is identical to the oligonucleotide of claim 7, which would make the claimed subject matter identical.

Conclusion

18. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

Art Unit: 1646

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
April 7, 2003

OL

Yvonne Eyler
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